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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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1660 UNION STREET
SAN DIEGO, CA 92101-2926

EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/996,629

Applicant(s)
Neeper et al.

Examiner
Dwayne K. Handy

Art Unit
1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any extended patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(e). 3
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Inventorship

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kedar et al. (6,083,761) in view of Farina et al. (4,244,694). Kedar teaches a device and method for combining chemical compositions or compounds in a multiwell plate. The system is best shown in Figures 5A-5E and 8A-10 and described in columns 10-12. The claims, starting with claim 15, recite a method of using the stacked device..

(20) System 1 may be configured to be either an open system or a closed system. When open, the regions R and locations L will preferably comprise open wells into which substances may be directly introduced. When closed, each of the regions R and locations L will be interconnected by micro-channels, by stacking the regions R over locations L, or the like. Various valves, including micro-valves, capillary holes, and other valves as described hereinafter, may be employed to regulate the transfer of fluids between the regions R and locations L using gravity, centrifugation, (using a centrifuge C) the application of positive or negative pressure, (using a pressure source P) and the like. Further, external input sources will be provided for introducing various reagents, chemical compositions, and the like into the system through fluid paths or micro-channels without exposing the system to the outside environment. In this way, the possibility of contamination and evaporation of the fluids will be greatly reduced. It will be appreciated that fluid introduction and transfer into and within the system may be controlled with a processor, e.g., to control application of pressure, the opening of valves, and the like.

(32) As best shown in FIG. 5C, capillary holes having a circular cross-section, such as capillary hole 34, are preferably offset laterally from apex 30 so that beads 32 will not tend to settle over capillary hole 34, thereby preventing the liquid medium from being transferred through capillary hole 34. Although it is preferred to have only a single capillary hole 34, additional capillary holes may optionally be provided in bottom ends 28. Capillary hole 34 may be provided with a noncircular profile. For example, as shown in FIG. 5G, capillary hole 34 has a triangular profile.

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(33) To draw the liquid medium through capillary hole 34, a centrifuge may be employed. In this manner, top plate 12 and bottom plate 14 may be spun at a rate which is sufficient to overcome the capillary forces and to draw the liquid medium from wells 16 into holding vessels 22. Alternatively, a vacuum may be provided at bottom ends 28 of wells 16 to draw the liquid into holding vessels 22.

(34) When employing a centrifuge or a vacuum, wells 16 may optionally be modified so that the capillary holes are configured to be transitory holes 34.div. as shown in FIGS. 5D and 5E. As illustrated in FIG. 5D, transitory holes 34.div. are normally biased closed. This is best accomplished by constructing bottom ends 28 of a flexible material which is normally biased toward the interior of wells 16. In this manner, holes 34.div. are normally closed to prevent fluids from draining. Upon centrifugation or application of a vacuum, holes 34.div. flex open as shown in FIG. 5E to allow transfer of the liquids. After centrifugation, holes 34.div. will again close.

Kedar then, teaches a method of loading the wells of a sample/collection container with reactants and supports, placing the sample collection container in a centrifuge, and spinning the sample/collection container at a speed to ensure that the liquid from the upper well moves through the capillary hole and into a collection well. Kedar does not teach centrifugation at a different speed than the first. Farina teaches a reactor/separator device for use in an automated solid phase immunoassay. The device is best shown in Figure 2 and is comprised of a column elements (10) held in a test tube (24). The column element is filled through centrifugation at a first speed to allow the reagents or reactants to come into contact with the material in the column. This first speed is enough to bring the reactants into contact with the immobilized material (22) contained within the column. The device is then spun centrifugally at a second speed which causes the reactants to pass through the media in the upper tube, through the exit of the upper tube, and into the collection tube. It would have been obvious to one of ordinary skill in the art to combine the

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dual speed centrifugation of Farina with the method of Kedar. Kedar already teaches the use of centrifugation to pass material through an upper well into a lower well. The addition of a step of centrifugation at a lower speed would allow for the use of centrifugation as a force for mixing the contents of the upper well before using a second, different centrifugation speed to transfer the content of the upper well to the lower well.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shapiro et al. (3,953,172), Mari et al. (6,488,860) and Van Vlasselaer (5,840,502) teach separation methods which use two or more centrifugation steps. Kedar et al. (6,054,325), Hsei (5,242,660), Goowin, Jr. (6,468,786), Lebl (6,121,054), Kuhl et al. (4,775,629), Schmitz (3,713,775), and Neeper et al. (6,503,457) teach devices or systems which use centrifugal force to move or transfer fluids.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

June 28, 2003
